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FILING DATE: *August 31, 1999*

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Chernoff, Vilhauer, McClung & Stenzel, LLP 600 Benj. Franklin Plaza, One S.W. Columbia, Portland, Oregon, U.S.A. 97258
Phone (503) 227-5631 • Fax (503) 228-4373

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PTO/SB/16 (2-98)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Romuald	Pawluczyk	362 Roselawn Place Waterloo, Ontario Canada N2L 5P1

☑ Additional inventors are being named on the 1 separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

Compact Device For Measuring Tissue Analytes

CORRESPONDENCE ADDRESS

Direct all correspondence to:

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OR Type Customer Number here

☑ Firm or Individual Name	Chernoff, Vilhauer, McClung & Stenzel, LLP				
Address	600 Benj. Franklin Plaza				
Address	One S.W. Columbia				
City	Portland	State	Oregon	ZIP	97258
Country	U.S.A.	Telephone	503-227-5631	Fax	503-228-4373

ENCLOSED APPLICATION PARTS (check all that apply)

☑ Specification Number of Pages 15
☐ Small Entity Statement
☑ Drawing(s) Number of Sheets 6
☒ Other (specify) Certificate of Mailing

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

☒ A check or money order is enclosed to cover the filing fees
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FILING FEE AMOUNT ($): $150.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Donald B. Haslett
Date Aug. 31/99

TYPED or PRINTED NAME Donald B. Haslett
REGISTRATION NO. (if appropriate) 28,855

TELEPHONE 503-227-5631
Docket Number: DBH:7468.006

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C., 20231.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

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Docket Number		Type a plus sign (+) inside this box →	+

INVENTOR(S)/APPLICANT(S)

Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Duncan	MacIntyre	120 Crawford Crescent Campbellville, Ontario Canada L0P 1B0
Bronislaw	Bednarz	832 Royal York Road Toronto, Ontario Canada M8Y 2T9

Number 1 of 1

CERTIFICATE OF MAILING

BY "EXPRESS MAIL"

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Date of Deposit : August 31, 1999

I hereby certify that the provisional patent application attached hereto entitled COMPACT DEVICE FOR MEASURING TISSUE ANALYTES, Romuald Pawluczyk, Duncan MacIntyre, and Bronislaw Bednarz, inventor(s), together with Provisional Application For Patent Cover Sheet Form PTO/SB/16 (sheets 1 and 2), drawings (6 sheets), and the required fees, is being deposited with the United States Postal Service "Express Mail to Addressee" on the date indicated above and is addressed to: Box Provisional Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

J. Lorraine Johnstone

Title: COMPACT DEVICE FOR MEASURING TISSUE ANALYTES

FIELD OF THE INVENTION

This invention relates to a compact device for non-invasively measuring concentration levels of blood constituents. The device includes a communications interface for interacting with a computer.

BACKGROUND OF THE INVENTION

Invasive techniques of measuring blood constituents are in common usage. These techniques are painful, potentially dangerous and expensive to operate. The normal procedure is to obtain a blood sample from a vein and this sample is then tested in a medical laboratory, using a number of chemical procedures to measure each constituent separately. Alternatively, home glucose testing uses a finger puncture that is spotted onto an enzyme-based semi-permeable membrane test strip and is allowed to react for a certain length of time, with insulin administration then based upon either a visual colour comparison with a standard colour chart or by means of a more accurate and unambiguous spectroscopic technique (for example reflectance). There is a risk of infection and sometimes a patient can develop a rash when these invasive techniques are used.

Previous devices for non-invasively monitoring concentrations of blood constituents of a patient are also known. These devices are used to externally measure either the concentration of the constituent in gases emitted by the body; the concentration contained in perspiration; or the concentration contained in body fluids such as tears, saliva, or urine samples; or, alternatively, the blood constituent is measured using radiation passed through a part of the patient's body such as the earlobe.

A recently developed and patented non-invasive method and device is described in U.S. Patent No. 5,361,758. '758 discloses a non-invasive method and device for monitoring the concentration levels of

one particular constituent or, alternatively, of measuring the concentration level of several different constituents simultaneously, the method and device producing results in a short time period that are highly accurate and compare favourably to invasive techniques.

Specifically, the non-invasive device and method disclosed in '758 measures concentration levels of blood and tissue constituents in a living subject such as a human or animal utilizing a polychromatic light source that emits light over a broad spectrum of wavelengths in the near infrared range. The light is passed through, or reflected from, a part of the subject such as a finger, ear lobe or other part of the body. That light is then separated into its various components by means of a grating or prism, and the near infrared band is focussed onto a linear array detector. A microprocessor uses the output of the array detector to measure the transported light (scattered light and possibly transmitted light), calculate the equivalent absorbance, and calculate the second derivative of the equivalent absorbance. A calibration equation is used for each constituent to be monitored to convert the second derivative measurements to a concentration level for that constituent. The device can be used to determine levels of various blood and tissue constituents, including glucose, cholesterol, alcohol, blood gases and various ions.

A finger receptor for use with a non-invasive monitoring device such as the one described '758 is disclosed in U.S. Patent No. 5,429,128. The finger receptor disclosed in '128 has a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source through a finger located in the channel in a direction generally normal to the finger. Extraneous light is excluded and the finger is held in position by a spring-mounted roller. The receptor has sensing means to determine when a finger has been properly positioned in the channel.

While the method and devices disclosed in '758 and '128 provide a significantly improved and effective non-invasive technique for monitoring the concentration of known constituents in blood or tissue,

there is a need for a device which is compact, efficient and portable, and which has improved stability and less sensitivity to problems created by heat.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a device for non-invasively monitoring concentration levels of blood constituents, the device being compact and efficient, and having improved stability and reduced sensitivity to heat. The device includes a communications interface for interacting with a computer and draws power from a stable external power supply.

In one aspect, the present invention provides an apparatus for non-invasively monitoring concentration levels of constituents in blood and tissue in a living subject such as a human or animal, said apparatus comprising:

a) a compact measuring device including:

i) a polychromatic light source that emits a broad spectrum of light in the near infrared range and adjacent visible light, said light source being coupled to and powered by a stabalized power source;

ii) a part receptor shaped for receiving a part of said subject, said part receptor having means for excluding extraneous light, said part receptor being located relative to said light source so that when part of said subject is placed in contact with the part receptor, said light source can be activated and light from said light source can be directed onto said part;

iii) a light receptor for collecting simultaneously a continuum of wavelengths over said broad spectrum after said light has been directed onto said part;

iv) means coupled to said light receptor for dispersing said collected light over said broad spectrum into a

dispersed spectrum of component wavelengths of said collected light;

v) a photodetector coupled to the device for taking absorbance measurements from said collected light at several different wavelengths simultaneously over said dispersed spectrum of component wavelenths, said photodetector producing a measurement signal; and

b) a computer for controlling at least one function of said compact measuring device, said computer being external to said compact measuring device and including means for receiving said measurement signal; and

c) an interface provided between said compact measuring device and said computer, said interface providing means for communication between said computer and said compact measuring device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram showing the relationships for various components of a device for non-invasively monitoring the concentration levels of blood constituents;

FIG. 2 is a perspective view of one embodiment of a device in accordance with the present invention;

FIG. 3A is another perspective view of the device of FIG. 2 showing some of the internal components of the device;

FIG. 3B is an exploded view of the device of FIG. 2, also showing the internal components of FIG. 3A;

FIG. 3C shows a schematic view of some of the main components of the device shown in FIGS. 3A and 3B; and

FIG. 4 is a block diagram showing the relationships between the device of FIGS. 2, 3A-3C and a computer system.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The basic principles of operation of non-invasive measurement technique used in the present invention is provided in U.S. Patent No. 5,361,758 which is incorporated herein by this reference.

'758 discloses that a near infrared region of the electromagnetic spectrum is particularly well-suited to in-vivo diagnostic applications because human tissue is essentially transparent to the incident radiation and therefore sufficient penetration of the radiation is possible to allow accurate quantitative analysis.

As shown in FIG. 1, a prior art non-invasive device for continuously monitoring concentration levels of blood and tissue constituents has a polychromatic light source. '758 discloses that the light source can emit light over a very wide bandwidth including light in the near infrared spectrum. (It has been recognized by the inventor that adjacent visible light outside of the range specified in '758 is also contributes information for in vivo diagnostic applications.) The light from the light source passes first through a collimator, which is a collection of lenses that concentrate the light into a narrow parallel beam directed at the receptor. The receptor is shaped to receive within it a part of the subject, for example, a finger or ear of a human. The light is directed onto the finger or ear and is dispersed by the finger or ear. The dispersed light is collected by lenses and directed through a slit to diffraction means. Preferably, the diffraction means is a diffraction grating or a holographic grating. The light from the grating disperses the light into its component wavelengths so that the light in the infrared region falls along the length of a linear array detector. The array detector has a series of diodes which is electronically scanned by a microprocessor to measure the intensity of light for each wavelength transmitted through or reflected from the tissue in the receptor. The detector is connected to the microprocessor, producing an output spectrum, with the microprocessor analyzing the measurements and ultimately producing a result for each concentration level determined. The result can be shown on a display and/or printed on a printer. The

keyboard allows a user to control the device, for example, to specify a particular constituent to be measured. The timing and control is activated by the microprocessor to control the device, for example, to determine number and timing of measurements.

It is disclosed in '758 that the polychromatic light source can be a quartz-halogen or a tungsten-halogen bulb and is powered by a stabilized power source, for example, a DC power supply, or by a battery. (The inventor has realized that photoluminescent sources of radiation may also be used.) This polychromatic light source may be a tungsten-halogen lamp or it may be a collection of LEDs or other light sources selected to emit radiation in the near infrared region (and adjacent visible light, as realized by the inventor). It should be noted that after activation of the light source, the scanning detector is read so that light is passed through the receptor and measured by the detector through the taking of a series of measurements at a selected wavelength.

In the system disclosed in '758, the microprocessor control activates and scans the linear array detector only after a detected pulse has occurred and the full spectrum measurements are then taken for the light after it passes through the receptor. Scanning is stopped when another pulse is detected on the selected wavelength. In other words, measurements are taken only when the blood pressure in the finger or ear or other part of the person is at a constant level.

In contrast, in the present invention, measurements are taken over some phase of a pulse, or are taken over several pulses, and an average of the resulting signal over the measurement period is calculated.

It is explained in '578 that in a further variation, the device can take all measurements regardless of the pulse of the subject. The microprocessor can then be controlled by computer software to select those measurements that are taken between pulses and to base the calculation of the concentration levels on the selected measurements. In a further variation, the measurements upon which the results are based, could be taken during pulses.

It is explained in '758 that the receptor has means for eliminating extraneous light. For example, where a finger is the part of a human through which the light passes, the receptor has an oblong shape similar to but larger than the shape of the finger. The means for eliminating extraneous light from the receptor is a flexible ring that surrounds an entrance to the receptor. When the finger is inserted, the flexible ring forms a seal around the finger when the finger has been inserted into the receptor. All surfaces within the device, including surfaces within the receptor are made non-reflective to minimize stray light. (The flexible ring forming the seal is optional and is not used in the present invention. However, measures have been taken to minimize stray light, as discussed further below.)

Finally, '758 discloses that, after the measurements are taken with a finger of the subject in place in the finger receptor, a reference set of measurements is taken of the incident light, being the light generated in the device when no part of the subject is in contact with the receptor. A ratio of the two measurements is then calculated.

Based on the principles of operation of a non-invasive monitoring device summarized above and disclosed in detail in '758, a new and improved compact device for non-invasively monitoring the concentration levels of blood constituents is shown in FIG. 2 and generally referred to by reference numeral 10. FIG. 2 shows an external perspective view of the device 10 with an instrument cover 20 and a hand support 200, and shows an opening 11 into which the hand of a user is inserted for taking a measurement of the user's blood or tissue constituents. Optional legs 210 allows the device 10 to sit in position on a flat surface.

Now referring to FIGS. 3A -3C, and referring back to FIG. 1, there is provided a polychromatic light source which may comprise a lamp 91 (FIG. 3C) within a lamp housing 90 (FIGS. 3A and 3B). The light source or lamp 91 in FIGS. 3A and 3B is able to generate light over a wide bandwidth including the near infrared regions, discussed earlier, and further including adjacent visible light.

While the '758 patent discloses the use of a collimator (FIG. 1) which uses a series of lenses to concentrate the light from the polychromatic light source into a narrow parallel beam, the present invention uses an elliptical reflector 94 to reflect and concentrate the light from the polychromaticlight source or lamp 91. A heat reflection filter 95 is provided within the elliptical reflector 94 to contain heat generated by the lamp 91.

Still referring to FIGS. 3A-3C, a multi-positional shutter 101 is provided between the lamp 91 and the first light guide 120 to further controls the light entering the first light guide 120, or otherwise filtering, attenuating, or blocking the light entering the first light guide 120. A stepping motor 100 is provided for rotating the multi-positional shutter 101 into one of a plurality of rotational positions. In one position, the multi-positional shutter 101 provides an opening 102 to allow light concentrated by the elliptical reflector into a first light guide 120. In another position, a plurality of very small holes 103 are provided to allow some of the light from the light source 91 to enter the first light guide 120. In yet another position, a filter 104 is provided which attenuates the light from the light source 91 entering the first light guide 120. In yet another position 105, the multi-positional shutter 101 entirely blocks the light from the light source 91. Various other means of attenuating or otherwise controlling the light entering the first light guide 120 may be provided on the multi-positional shutter 101.

Still referring to FIGS. 3A-3C, a the first light guide 120 guides the beam of light to a finger receptor 70, 140. The operation of the finger receptor 70, 140 is described in detail in U.S. Patent 5,429,128 which is incorporated herein by this reference. As disclosed in '128, the finger receptor 70, 140 receives a finger of a user into a channel, and the beam of light guided by the first light guide 120 is directed generally normally to the finger of the user inserted into the finger receptor 70, 140. As further disclosed in '128, and described above, the finger receptor 70,140 includes a sensing means to determine when a finger had been properly positioned

in the channel and acts to excludes extraneous light which would interfere with the signal received by the light receptor (FIG. 1).

In order to further reduce the amount of extraneous light entering the light receptor (FIG. 1), the device cover 20 has been designed to substantially cover the finger receptor and other components within the device housing 20, 30. When a hand of a subject is inserted into the opening 11 (FIG. 2), a substantial portion of the extraneous light is blocked out.

Light which passes through the finger receptor 70, 140 is received by a light receptor (FIG. 1) which in FIGS. 3A and 3B comprises a second light guide 130 which guides light to a light guide adapter 170 and to a spectroscope 180. The light is then detected by a thermostabalized and/or cooled photodetector array assembly 190 which includes a photodetector array 191, electronics 192A to control a thermoelectric cooler and electronics 192B to digitize the signal received by the photodetector array 191, and a heat sink 193 including a thermoelectric cooler to dissipate heat.

Preferably, the electronics in the photodetector array assembly 190 provides analog to digital conversion of the light signal received by the photodetector array 190 for transmission to a computer. Sending an analog signal to a computer for processing and conversion is less preferred since an analog signal is more susceptible to electromagnetic interference radiation produced by the various components and the computer.

As explained earlier, the device 10 shown and described in FIGS. 3A and 3B (and shown in block diagram form in FIG. 1) requires stable operating conditions to function optimally. One component which is important to stability of the device 10 is a stable power supply with a large power reserve.

In previous devices, such a power supply is typically provided within the device, and the heat generated by the power supply and other internal components has the potential to affect the stability and accuracy of the device.

In order to provide a compact, high-performance device with improved stability, the device 10 shown and described in FIGS. 2 to 4 operates on a power supply which is external to the device 10. As the device 10 is designed to interface with a computer 300 ((FIG. 4), preferably, the device 10 will draw power from the computer power supply 311. A power conditioner 320 may be provided between the computer power supply 311 and the device 10 in order to provide a stable, clean power source for the device 10.

Referring back to FIGS. 3A-3C, the component which will generate the most heat within the device is the lamp within the lamp housing 90. In order to minimize the effect of the heat generated by the lamp and lamp housing 90, a lamp heat screen 50 is provided between the lamp housing 90 and the other components in the device, including the electronics 40, the spectroscope 180 and the photodetector array 190. Furthermore, an electronics board 60 to control the multi-positional shutter 101 also provides a shield to the electronics 40 from the heat conducted by the multi-positional shutter housing 115 from the lamp 91.

Advantageously, by shielding the heat generating lamp housing 90 from the other components in the device, and by removing the power supply so that the power supply is external to the device (preferably the computer power supply 320), the heat generated within the device housing 20, 30 is significantly reduced. Heat which is produced within the housing 20, 30 is dissipated by the heat sink provided with the photodetector array 190 and is also removed from the device housing 20, 30 by means of cooling fans 150 and 160 and vents 21.

As a result of the heat generated in the housing 20, 30 being significantly reduced, and as a result of the reduced electronic noise in the electronic circuits in the device 10, a less powerful light source can be used in the device 10. That is, the lamp (e.g. quartz-halogen or tungsten-halogen lamp) used for the light source may be less powerful while the same level of measurement sensitivity is retained (because of the lower noise level in the electronic circuits) as compared to a device with an

internal power supply.

Also, by allowing the computer 300 (FIG. 4) interconnected to the device 10 to process many of the control functions for the device 10, the electronics 40 required within the device 10 can be minimized to basic control and communications functions. In effect, the device 10 may then be operated as if it was a peripheral device to a computer, with the main function of the device 10 being for providing a light source, a light receptor, and providing raw data resulting from the measurement for further processing.

In a preferred embodiment, the device 10 is interconnected to a computer by means of a customized computer interface card 320. For example, the computer interface card 320 may be built to interconnect with an industry standard PCI (Peripheral Circuit Interconnect) bus or an ISA (industry standard architecture) bus, both of which are common to many personal computer systems presently available. For use with a portable laptop computer system, a suitable customized computer interface card may be developed to the PCMCIA industry standard. The computer interface card 320 may receive analog data from the device 10 and covert the analog signal to a digital signal for processing by the computer 300.

A connection for the device 10 via other industry standard interfaces such as parallel or serial ports, SCSI and USB ports is also possible, although such options may require additional electronics to be placed within the device housing 20, 30 and thus increase the heat generation within the device 10. Nevertheless, a benefit of such a connection to a parallel, serial, SCSI or USB port is that the installation of a card into a computer may not be required.

As explained, the interconnection of the device 10 to a computer 300 facilitates controlling the device 10 using software means running in memory 330 and the microprocessor 340 and optionally stored in storage 380 in the computer 300. Furthermore, the software means may provide a user with a graphical user interface on a suitable display 350 including step-by-step instructions for operating the device 10.

The software means may also control receiving and analyzing data collected by the device 10 and may display measurement results graphically on the computer display 350 or optionally print out the results on a printer 355. A series of results may be stored in storage 380 for further processing or recall. The device 10 may be controlled by means of an input, such as a keyboard 360 or a mouse 370, among many other possible input devices.

In summary, by generally limiting the device 10 to the essential components for providing a light source, and measuring the light which passes through a finger placed in the finger receptor 70, 140, the device 10 is significantly reduced in size and cost. Also, by significantly reducing the heat generated in the device, cooling requirements are reduced and the device 10 is less sensitive to heating problems, thereby improving the stability and accuracy of the device. Also, by transferring the control interface and analysis onto a computer 300, the processing power of the computer 300 is used to enhance the user interface and to enhance analysis of the raw data collected by the device 10.

While one embodiment of a device according to the present invention has been shown and described, it will be appreciated that changes and modifications are possible without departing from the scope of the invention which is defined by the following claims.

WE CLAIM:

1. An apparatus for non-invasively monitoring concentration levels of constituents in blood and tissue in a living subject such as a human or animal, said apparatus comprising:

a) a compact measuring device including:

i) a polychromatic light source that emits a broad spectrum of light in the near infrared range and adjacent visible light, said light source being coupled to and powered by a stabalized power source;

ii) a part receptor shaped for receiving a part of said subject, said part receptor having means for excluding extraneous light, said part receptor being located relative to said light source so that when part of said subject is placed in contact with the part receptor, said light source can be activated and light from said light source can be directed onto said part;

iii) a light receptor for collecting simultaneously a continuum of wavelengths over said broad spectrum after said light has been directed onto said part;

iv) means coupled to said light receptor for dispersing said collected light over said broad spectrum into a dispersed spectrum of component wavelengths of said collected light;

v) a photodetector coupled to the device for taking absorbance measurements from said collected light at several different wavelengths simultaneously over said dispersed spectrum of component wavelenths, said photodetector producing a measurement signal; and

b) a computer for controlling at least one function of said compact measuring device, said computer being external to

said compact measuring device and including means for receiving said measurement signal; and

c) an interface provided between said compact measuring device and said computer, said interface providing means for communication between said computer and said compact measuring device.

ABSTRACT OF THE DISCLOSURE

A compact device for non-invasively monitoring concentration levels of blood constituents, including glucose, cholesterol, alcohol, blood gases and various ions. The device includes a finger receptor having a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source through a finger located in the channel in a direction generally normal to the finger. Certain heat generating components, including a stable power supply for the device, are external to the device housing so as to reduce heat generation and thereby increase stability of the device. The device includes a communications interface for interacting with a computer. The device can be used for clinical use or for home use and the memory of the computer can be used to assist with record keeping and with dosage calculations.

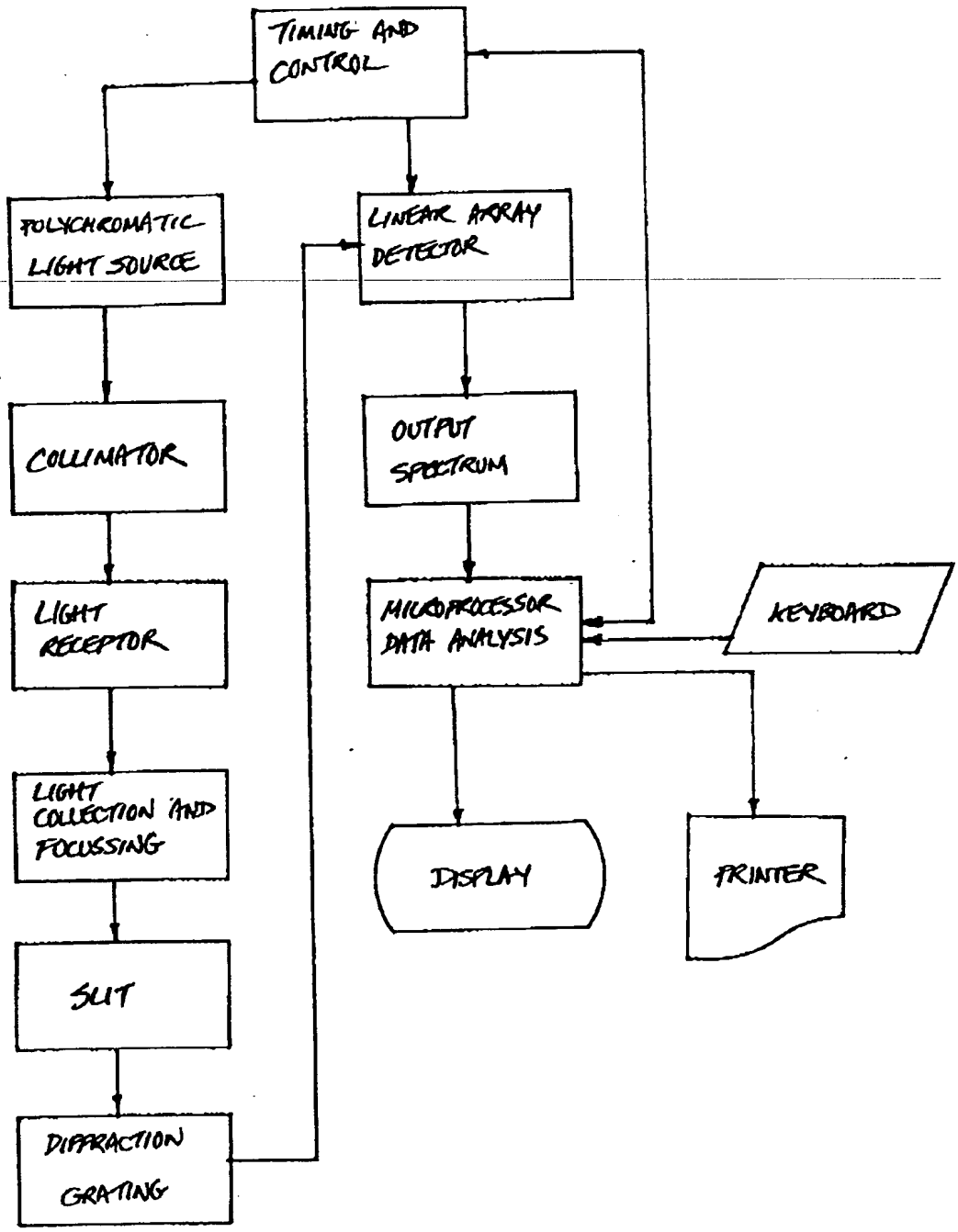

FIG. 1 (PRIOR ART)

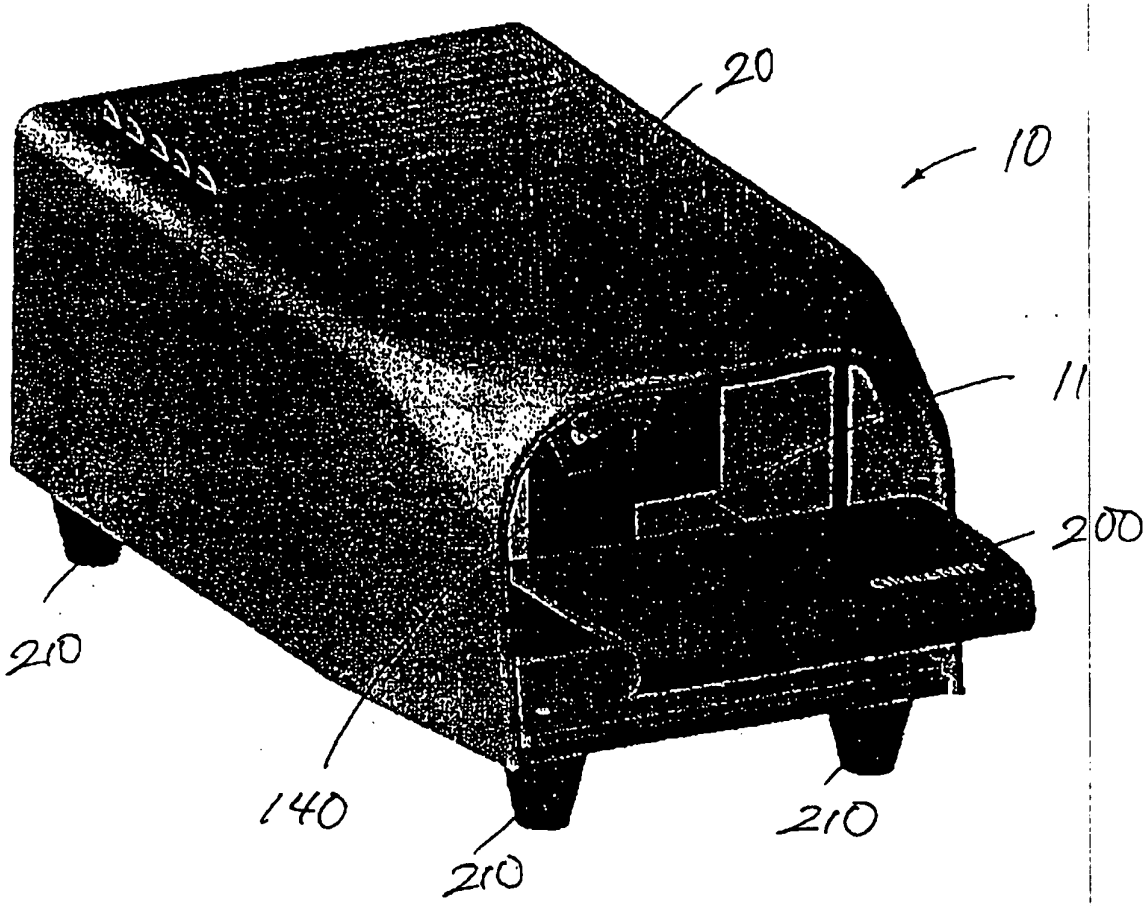

FIG. 2

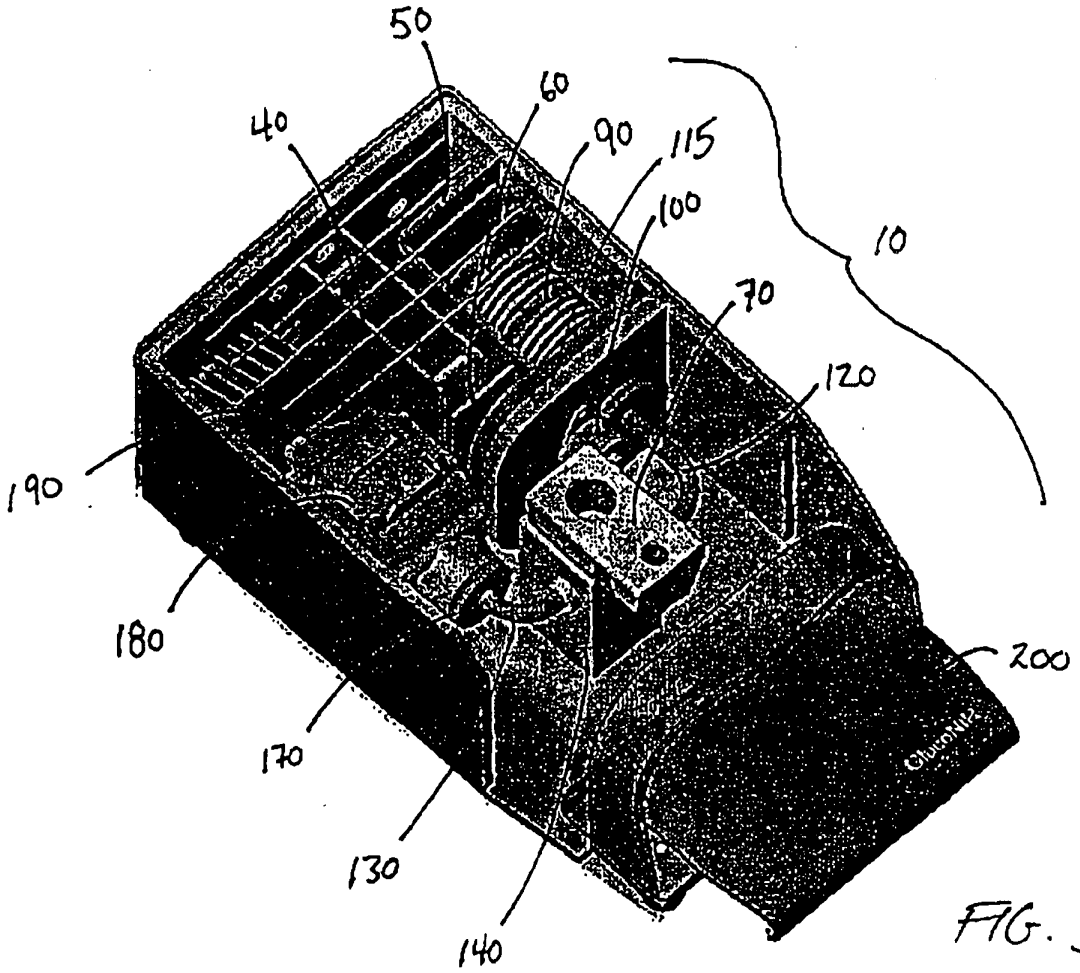

FIG. 3A

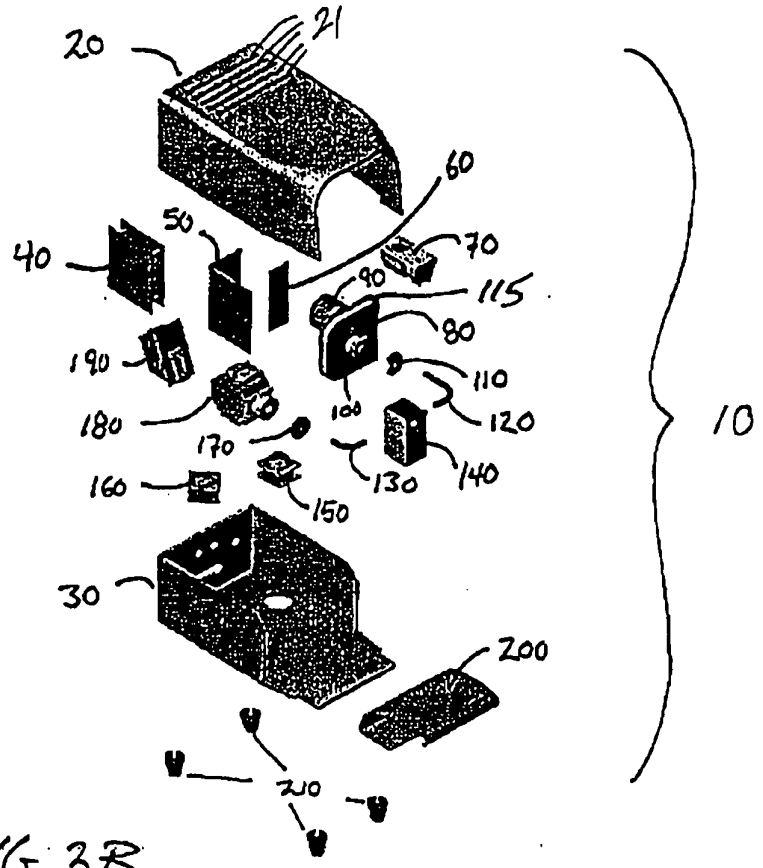
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FIG. 3B

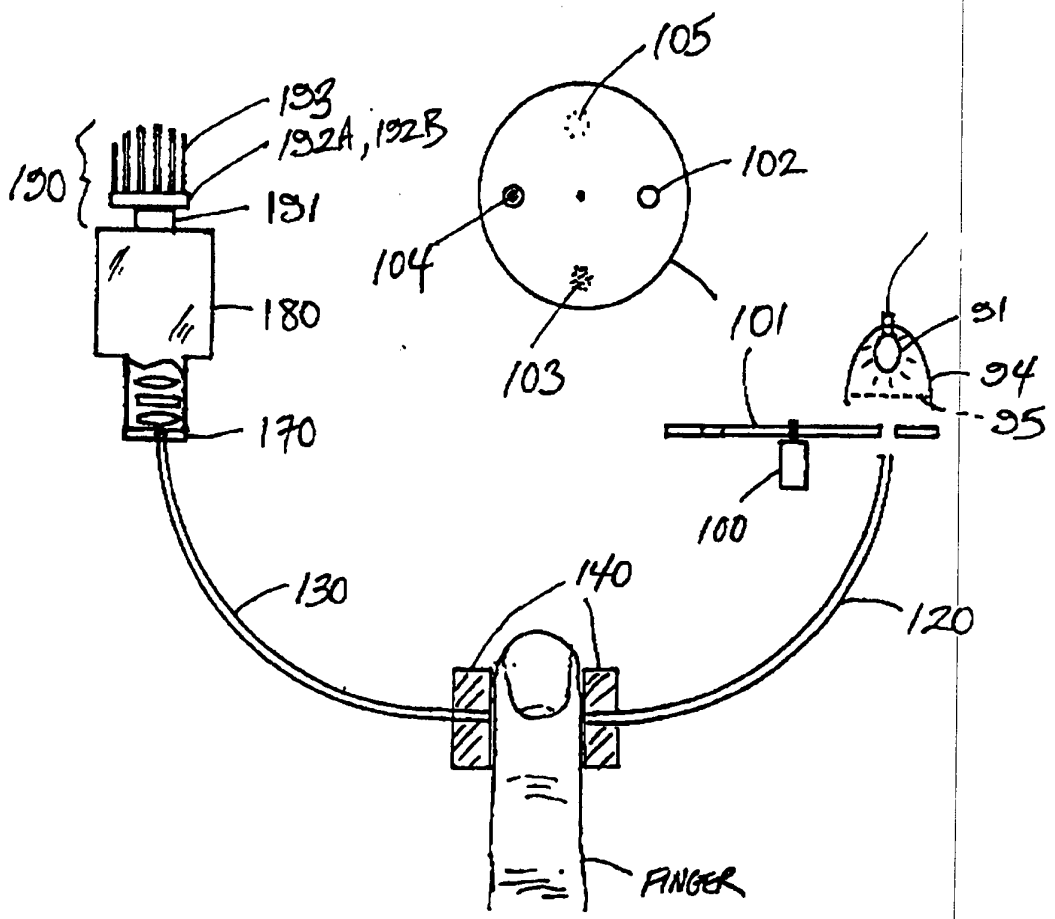

FIG. 3C

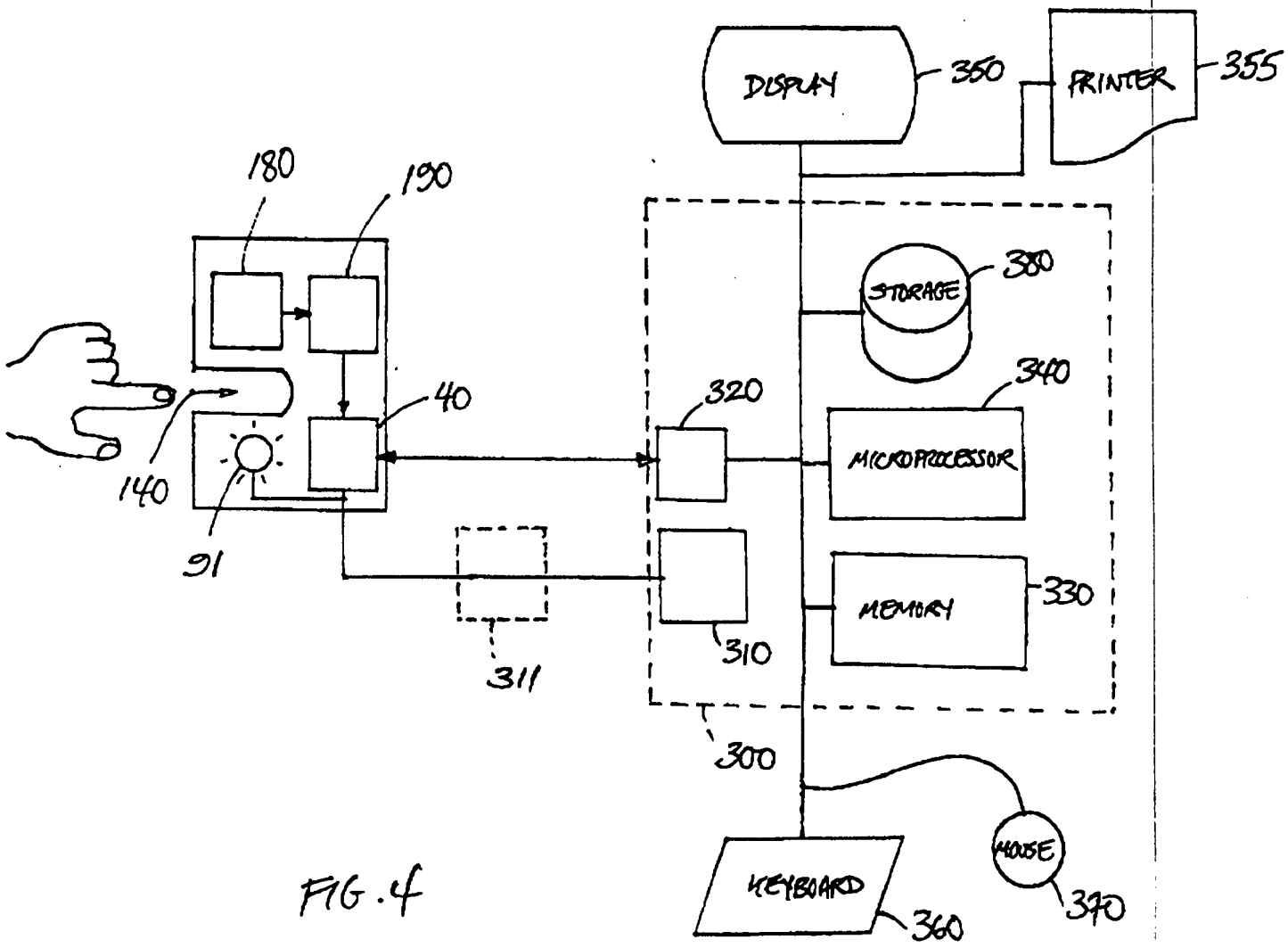

FIG. 4